

Ethical guidelines in research on mentally incompetent patients

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1. In medical research, the subject should sign the consent form wilfully. If for any reason the subject can not make a decision, the patient's legal guardian must sign the consent form.
2. Further attempts should be made to get the subjects' signature in case there is improvement in their condition.
3. If for any reason the subject can not decide for himself but he can introduce another person for decision making, he has to select the substitute person.
4. Refusal of contribution in a project even by a mentally incapacitated patient is accepted and he/she should not be enrolled in the research.
5. The patient's personal physician, who is not part of the research team can judge about the patients capacity, otherwise an unrelated physician has to mediate.
6. Mentally retard patients may participate in researches that have direct and considerable benefits for them.
7. In some situations, if the project does have the least injuries or does not have direct benefit for patient, but has benefits for his mates, and the results are applicable for the other groups, the patient can be enrolled in the research by his/ her guardians sign.
8. Since the keeper has the responsibility, the data must be published by his agreement.
9. If revealing results to the guardian and relatives can have positive or negative effects on the patient, this has to be mentioned.
10. In problematic situation which making decision about patients confidentiality is on debate, ethical committee has to decide.
11. Non-disclosing patients information to his/her guardian based on patients request should be decided by ethics committee.
12. In observational research in which there is no risk, the patient or his/her guardian must be informed about the participation of the patient in the project, and the subject must sign the consent form, otherwise the ethics committee must decide.
13. In case of severe emotional problems such as suicide, the patient must be excluded from the project. Also supportive care should be considered for him. In case of a history of severe emotional problems, the patient must be excluded from the study.
14. Hazardous studies can be conducted on mentally retarded patients if there is no other alternative and it can not be performed on healthy subjects.